



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

**NOTICE OF ALLOWANCE AND ISSUE FEE DUE**

020350 UM22/0831  
TOWNSEND AND TOWNSEND AND CREW LLP  
TWO ENBARCADERO CENTER  
3TH FLOOR  
SAN FRANCISCO CA 94111-3834

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/476,798	06/07/95	007	HAUDA, K	1632 08/31/95
First Named Applicant	DEBOER, 35 USC 154(b) term ext. = 0 days.			

TITLE OF INVENTION PRODUCTION OF RECOMBINANT POLYPEPTIDES BY BOVINE SPECIES AND TRANSGENIC METHODS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	16994-003125	800-015,000	ASH UTILITY	NO	\$1210.00	11/30/95

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

**I. Review the SMALL ENTITY status shown above.**

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

**II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.**

**III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.**

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

PATENT AND TRADEMARK OFFICE COPY

# Notice of Allowability

Application No.  
**08/476,798**

Applicant(s)

**Deboer et al.**

Examiner

**Karen M. Hauda**

Group Art Unit

**1632**



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to May 24, 1999

☒ The allowed claim(s) is/are 114-120

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 12

☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

*Karen M. Hauda*  
**Karen M. Hauda**  
Patent Examiner

Application/Control Number: 08/476,798

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**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joe Liebeschuetz on August 26, 1999.

The application has been amended as follows:

In claim 114, line 2, the term "~~nucleic acid~~" has been inserted before the first occurrence of the term "construct".

In claim 114, line 7, the term "~~and~~" has been deleted.

In claim 114, line 8, the term "~~interest,~~" has been replaced with the phrase "interest; and".

In claim 114, line 15-16, the phrase "a bovine protein undetectable in milk of a natural bovine, or a heterologous polypeptide" has ~~been~~ replaced with the phrase "heterologous to the milk of a natural bovine".

Claim 118 has been rewritten as follows.

Claim <sup>5</sup>118. A method of producing a chimeric bovine, the method comprising:

obtaining an ovum from bovine ovaries;

maturing the ovum *in vitro*;

61

176

6

61 (cont.)  
fertilizing the mature ovum *in vitro* to form a zygote;

introducing into the zygote *in vitro* a nucleic acid construct comprising in operable association a DNA sequence encoding a signal sequence functional in bovine mammary gland secretory cells, a DNA sequence encoding a polypeptide of interest, and a regulatory sequence that promotes expression of the DNA sequence encoding the polypeptide of interest;

maturing the zygote to a preimplantation stage embryo *in vitro*; and

transplanting the embryo into a recipient female bovine, wherein the female bovine gestates the embryo to produce a chimeric bovine.

In claim 119, line 1, the phrase "~~comprising~~ the polypeptide of interest" has been inserted after the term "milk".

In claim 119, line 2, the phrase "~~comprising~~ the polypeptide of interest" has been replaced with the phrase "of the bovine".

In claim 120, line 8, both occurrences of ~~the~~ term "transgenic" have been deleted.

In claim 120, line 10, the term "~~transgenic~~" has been deleted.

In claim 120, line 11, the term "~~transgenic~~" has been deleted.

In claim 120, line 12-13, the phrase "~~bovine~~ protein undetectable in milk of a natural bovine, or a" has been deleted.